GOVERNMENT OF INDIA
CHEMICALS AND FERTILIZERS
LOK SABHA

UNSTARRED QUESTION NO:4610
ANSWERED ON:06.08.2009
CHANGE IN BODY REGULATING PHARMACEUTICAL ACTIVITIES
Adhalrao Patil Shri Shivaji

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether there is any proposal to bring about changes to the body that regulates the manufacture, import, storage, promotion and use of medicines, cosmetics and other pharmaceutical products;

(b) if so, the details in this regard;

(c) the time by which these changes are likely to be made effective; and

(d) the extent to which the new structure is able to tighten the lax manufacturing practices?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS(SHRI SRIKANT KUMAR JENA)

(a) to (d) The Drugs and Cosmetics (Amendment) Bill 2007, introduced in the Rajya Sabha on the 21-08-2007, contains provisions for inter alia creation of an autonomous drug regulatory authority, namely, the Central Drugs Authority in place of the existing Central Drugs Standard Control Organisation (CDSCO). The Central Drugs Authority would undertake the regulatory functions in respect of drugs, cosmetics and medical devices under the provisions of the Drugs and Cosmetics Act, 1940 like import, manufacture, storage, distribution etc., which is presently done by the CDSCO. It would also undertake the functions of the Central Licensing Authority for which the said Bill contains the enabling provision by transferring this responsibility from State Governments. The said Bill is presently pending in the Rajya Sabha.